K132108
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510(k) Summary

MAY 19 2014

1. Manufacturer/Applicant Name: Perfint Healthcare, Pvt. Ltd.,
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   India
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   Contact: Nandakumar Subburaman, CEO

2. Contact person: Janice Hogan (Hogan Lovells US LLP)
   Phone number: (267)675-4611
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3. Trade name: MAXIO™
   Common name: CT stereotactic accessory
   Classification name: Computed tomography x-ray system
   Classification: 21 CFR Part 892.1750 Class II
   Product Code: JAK

4. Date prepared: May 14, 2014

5. Substantial equivalence claimed to: ig4 Image Guided System (K060903)
   PinPoint (K974513)

6. Device Description

MAXIO™ is an image-guided, physician controlled stereotactic accessory to a Computed Tomography (CT) system, intended for the stereotactic spatial positioning and orientation of an end effector and instrument guide to assist in manual advancement of one or more instruments such as rigid straight needles and probes during CT guided percutaneous procedures on organs and anatomical structures in the thorax, abdomen and pelvis.
MAXIO™ System provides pre-operative planning assistance to the physician by creating a reconstructed 3D image model of received CT data and by visually representing the planned instrument path and position(s) of one or more instruments on the model, along with performance data provided by the instrument manufacturer or as specified by the user.

MAXIO™ permits physician verification of patient position prior to needle advancement and monitoring of respiratory for levels during the procedure. Image registration and overlay tools available in MAXIO™ are intended to provide guidance to the user during

planning and instrument placement. MAXIO™ is intended to be used by physicians trained for CT procedures.

MAXIO™ consists of a stereotactic device and its accessories, software loaded on a computer, and a respiratory gating system. The accessories include a patient immobilizer and skin-markers. MAXIO™ System uses single use sterile disposables viz, end effector, instrument guide and drapes.

7. Intended Use

MAXIO™ is a user controlled, stereotactic accessory intended to assist in the planning and manual advancement of one or more instruments during Computed Tomography (CT) guided percutaneous procedures.

MAXIO™ permits physician verification of patient position prior to needle advancement and monitoring of respiratory levels during the procedure. Image registration and overlay tools available in MAXIO™ are intended to provide guidance to the user during planning and instrument placement.

MAXIO™ is indicated for use with rigid straight instruments such as needles and probes used in Computed Tomography (CT) guided percutaneous interventional procedures performed by physicians trained for CT procedures on organs and anatomical structures in the thorax, abdomen and pelvis.

8. Substantial equivalence

MAXIO™ has been shown to be substantially equivalent to ig4 Image Guided System (K060903) for providing planning assistance by visually representing the targeted path and position(s) for one or more instruments along with data provided by the instrument manufacturer, on an image based model of the target organ and for providing verification assistance by overlaying or registering images during and after image guided procedures.

MAXIO™ has been shown to be substantially equivalent to PinPoint (K974513), which provides a multi axis electromechanical arm for the spatial positioning and orientation of an instrument guide to assist in manual advancement of instruments through the guide for image guided interventional procedures.

A comparison of technological characteristics of MAXIO™ with its predicates is shown in Annexure to 510K summary on Pg.15.

9. Performance Data

Bench tests performed using static phantom in accordance with Perfint's Quality Management System demonstrate that the accuracy targets of the MAXIO™ system were met and the system is suitable for its intended use.

Segmentation and Registration accuracy were demonstrated through adequate bench testing and also through clinical experience of qualified users.

Usability studies with qualified users were conducted in accordance with HE75 AAMI / ANSI HE75:2009, Human factors engineering - Design of medical devices.

Device Safety tests were performed in accordance with IEC 60601-1, 3rd edition, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

EMI / EMC testing performed in accordance with IEC 60601-1-2, 3rd edition, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility.*

The laser pointer used for verification of registration complies with 21CFR1040.10 and 1040.11 – Performance standards for light-emitting products.

Biocompatiblity testing of all disposables that might come in contact with the patient directly or indirectly have been tested in accordance with ISO 10993-1- *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.*

Disposables that are supplied sterile meet all the relevant/applicable IEC and FDA standards of sterilization, packaging and shelf life.

Ability of a physician to adequately intervene to pull back an instrument or to release the instrument for the stereotactic arm in case of gross patient movement during needle insertion has been tested at Memorial Sloan Kettering Cancer Center.

Effectiveness of skin marker / laser alignment to detect patient movement and the correlation between skin marker and anatomy to establish anatomical accuracy was verified under a CRO supervised study performed by Perfint Engineers on 14 patients at Global Hospitals, Chennai India

170 CT Guided Interventions performed by users of MAXIO outside of the USA has been analysed and report included to demonstrate accuracy and repeatability of MAXIO stereotactic performance under clinically relevant and worst case conditions

A 20 patient, 40 tumor liver ablation study performed at the University of Malaya Medical Center, Kuala Lumpur demonstrates accurate needle placement using MAXIO for CT guided Tumor ablations

An animal study performed at Memorial Sloan Kettering Cancer Center demonstrates that the accuracy of needle placement with MAXIO assistance is comparable to freehand placement by experts however fewer needle manipulations, check-scans

10.Conclusion

Information provided in this 510K notification demonstrate that the MAXIO™ is substantially equivalent to ig4 Image Guide System (K060903) for planning and verification assistance and to PinPoint (K974513) for assistance in manual advancement of instruments, for CT guided percutaneous interventional procedures. The indications for use and technological characteristics of the MAXIO™ System are similar to those of its predicates ig4 Image Guide System (K060903) and PinPoint (K974513).The differences from the Predicates do not raise any new questions of safety and effectiveness as confirmed by the Performance testing results.

Annexure to 510K summary

A comparison of technological characteristics of MAXIO™ with its predicates is shown below.

	Device		
Technological Characteristics	**MAXIO™**	**PinPoint**	**ig4 Image Guided System**
	K132108	**K974513**	**K060903**
Stereotactic device	Physician controlled multi-axis electromechanical arm	Physician controlled multi-axis electromechanical arm	Physician controlled electromagnetic tracking system
Image type	DICOM CT images (If received from more than one series, then registered)	DICOM CT images	DICOM CT images (If received from more than one series, then registered)
Image models	2D / MPR/ 3D Volume / Segmented views	2D / MPR views	2D / MPR/ 3D Volume / Segmented views
Type of instruments supported	Rigid, straight Interventional instruments such as needles, probes for biopsy, ablation and drainage.	Interventional instruments for biopsies, drainage, bone pinnings, brachytherapy, bone and spine interventions	Interventional instruments such as biopsy needles, ablation needle, aspiration needles
Pre-Operative Planning	Physician created trajectory on image models	Physician created trajectory on image models	Physician created trajectory on image models
Instrument performance display	Manufacturer and user defined instrument performance such as ablation size	None	Manufacturer and user defined instrument performance such as ablation size
CT- Device registration	Docking relative to CT on floor	Docking relative to CT on Gantry	Electromagnetic registration
Verification of registration	Laser pointer directed on pre-identified points on patient, CT (compliant with 21CFR 1040)	Laser pointer directed on pre-identified points on patient	EM probe directed on pre-identified points on patient
Assistance for instrument advancement	Arm aligns an end-effector to plan, using motors. Instrument then manually advanced through the guide gripped by the end-effector.	Arm manually assisted to align an instrument guide to the plan. Instrument then manually advanced through the guide gripped by the end-effector.	EM tracked instrument aligned manually to plan and then manually advanced through the guide.
Intraoperative verification	Image registration to compare current position to plan	Not available	Instrument tracking to compare current position to plan
Post-procedure verification	• Post procedure CT image • Image registration or overlay	Post procedure CT image	Post procedure CT image
No. of probes supported for a procedure	Multiple instruments. Planning assistance software alerts for possible arm – instrument, instrument – instrument interference	Single instrument	Multiple instruments, user takes care of possible instrument – instrument interference
Management of respiratory motion	Respiratory Motion control using *Breath-Hold* for Interventional Radiology	No solution described	Respiration tracking system using EM tracking.

	Device		
Technological Characteristics	**MAXIO™**	**PinPoint**	**ig4 Image Guided System**
	K132108	**K974513**	**K060903**
Management of patient movement	CT belt and optional patient immobilization bed	CT belt	CT belt
Instrument release during procedure	Instantaneous removal by clinician with no additional device action. Alternatively, through foot switch control or emergency button.	Instantaneous removal by clinician with no additional device action.	Instantaneous removal by clinician with no additional device action.

Discussion of differences:

Mounting the device to the floor mat using InstaReg in MAXIO™ achieves the same purpose of bringing the arm repeatedly to the same point as permanently fixing the arm to the CT Gantry in predicate PinPoint (K974513). Floor mounting and Ceiling mounting are commonly employed docking techniques in the industry and this dissimilarity does not raise additional safety and effectiveness issues.

Using motors to move the axes of an electromechanical arm, as done in MAXIO™, is a well established practice in the motion control industry. Alternatively the axes can be moved manually as in the predicate PinPoint (K974513).

MAXIO™ uses a well established collision avoidance algorithm to prevent arm – instrument and instrument – instrument interference, in addition to the physician assessing any possible interference prior to placement and arm pullback.

For procedure planning, MAXIO™ provides the physician the ability to plan needle placement on current CT images and on registered images from multiple series. Predicates ig4 (K060903) and Pinpoint (K974513) to allow planning only on current CT images. The registration feature offered by MAXIO™ is a well understood and commonly deployed technique in image guided procedures. In addition MAXIO™ registration accuracy has been bench tested and found acceptable.

For verification, MAXIO™ and its predicates ig4 (K060903) and Pinpoint (K974513) provide physicians the ability to visualize instrument(s) or targets using current CT images. In addition MAXIO™ provides intra-operative CT image registration with plan images to verify instrument position, whereas ig4 (K060903) uses electromagnetically tracked instruments to verify instrument position. MAXIO™ provides similar registration of post-procedure CT images to

compare the treated organ with plan. The registration feature offered by MAXIO™ is a well understood and commonly deployed technique in image guided procedures. In addition MAXIO™'s registration accuracy has been bench tested and found acceptable.

In addition all disposables that may come in contact with the patient or the user, directly or indirectly, have been tested in accordance to the US standards prior to commercial marketing of the device.

In addition, MAXIO™ has been bench tested to demonstrate that it meets the performance requirements for its intended use. Additionally, the following data demonstrates that MAXIO™'s stereotactic navigation is accurate and repeatable across various clinically relevant conditions:

- An analysis of 170 needle placements performed using MAXIO™ outside of the USA.
- A 20 patient study using MAXIO™ for liver ablation.
- A 35 needle placement study using MAXIO™ on 6 animal liver targets.

Therefore it has been concluded that the MAXIO™ is substantially equivalent to its predicates ig4 Image Guided System (K060903) and PinPoint (K974513) for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 19, 2014

Perfint Healthcare Pvt. Ltd.
% Ms. Janice M. Hogan, Partner
Hogan Lovells US LLP
1835 Market Street, 29th Floor
PHILADELPHIA PA 19103

Re: K132108
Trade/Device Name: MAXIO™
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: May 15, 2014
Received: May 15, 2014

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara For

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132108

Device Name
MAXIO™

Indications for Use *(Describe)*
MAXIO™ is a user controlled, stereotactic accessory intended to assist in the planning and manual advancement of one or more instruments during Computed Tomography (CT) guided percutaneous procedures.

MAXIO™ permits physician verification of patient position prior to needle advancement and monitoring of respiratory levels during the procedure. Image registration and overlay tools available in MAXIO™ are intended to provide guidance to the user during planning and instrument placement.

MAXIO™ is indicated for use with rigid straight instruments such as needles and probes used in Computed Tomography (CT) guided percutaneous interventional procedures performed by physicians trained for CT procedures on organs and anatomical structures in the thorax, abdomen and pelvis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Michael D. O'Hara

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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